LAPAROSCOPIC RECONSTRUCTIVE TUBAL SURGERY IN A TERTIARY REFERRAL CENTRE — A REVIEW OF 177 CASES

S J Dyer, S K Tregoning

Objectives. To establish the pregnancy rate (PR) following endoscopic reconstructive tubal surgery in patients with tubal disease presenting to the Reproductive Medicine Unit at Groote Schuur Hospital between January 1994 and December 1997.

Design. A prospective descriptive study utilising the Hulka classification system of tubal disease scored at the time of surgery and correlating the findings and procedures carried out with the pregnancy outcome.

Setting and subjects. Patients with infertility referred from level 1 and 2 health care facilities in the Western Cape to the Reproductive Medicine Unit in the Department of Obstetrics and Gynaecology at Groote Schuur Hospital.

Outcome measures. The main outcome measure was the PR following reconstructive surgery. Secondary outcome measures included the number of patients undergoing assisted reproductive techniques (ART) and the outcome of *in vitro* fertilisation and embryo transfer (IVF/ET).

Results. The results of 177 patients were analysed. The spontaneous PR for these patients was 13.6% per patient, with a live birth rate of 9%. The spontaneous extra-uterine pregnancy rate was 3.4% per patient and accounted for 25% of all spontaneous conceptions. Twenty-five patients (14% of the study population) underwent IVF/ET resulting in a PR of 36% per patient and 33.3% per embryo transfer.

Conclusions. The poor PR following endoscopic tubal reconstruction is predominantly attributed to the severity of tubal damage in the study population. Patients undergoing IVF/ET had a favourable PR — indicating that most of these couples are highly fertile but for the mechanical obstruction. The results of our study support ART as first-line therapy in the majority of patients with tubal factor infertility in the setting of this study.

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Reproductive Medicine Unit, Department of Obstetrics and Gynaecology, University of Cape Town

S J Dyer, MB ChB, MMed (O et G), FCOG

S K Tregoning, MB BCh, BSc (Hons), FCOG

Infertility, as part of childlessness, is a major reproductive health problem in Africa. Prevalence rates are high, the underlying disease commonly affects women's health over and above causing infertility and the psychosocial consequences are often severe.[1-4] Tubal infertility, secondary to sexually transmitted diseases and pregnancy complications, remains the commonest cause of female infertility in Africa. The therapeutic approach to tubal infertility is therefore of considerable importance for women's reproductive health on our continent. For many years surgery was the only therapeutic option available. Surgical techniques have advanced considerably, from macrosurgery to microsurgery and from open to endoscopic surgery. At present most authors consider laparoscopy to be the procedure of choice for reconstructive tubal surgery due to excellent postoperative patient recovery, the reduction of *de novo* adhesion formation, and success rates that compare favourably with open microsurgery.[5-10] However, reported pregnancy rates (PR) following laparoscopic tubal surgery vary widely (from 20% to over 70%).[6,8-13] Few studies are truly comparable and the absence of controlled data makes it difficult to draw any firm conclusions about the success of this form of treatment. In the absence of consensus it has been recommended that each institution should establish its own conception rates in order to counsel patients adequately.[14] More recently, the advent of assisted reproductive techniques (ART) and its current rate of success has further challenged the role of reconstructive tubal surgery in the treatment of tubal infertility.[15-17]

The aim of this study was to establish conception rates following endoscopic tubal surgery in patients with tubal disease presenting to the Reproductive Medicine Unit at Groote Schuur Hospital in Cape Town, South Africa. Pregnancy rates stratified for type and degree of pathology encountered and the outcome of ART in the same group of patients were secondary outcome measures.

PATIENTS AND METHODS

The pregnancy outcome of endoscopic reconstructive tubal surgery undertaken between January 1994 and November 1997 in the Reproductive Medicine Unit at Groote Schuur Hospital, Cape Town, was analysed. Patients were excluded from this analysis if no pelvic pathology was found at laparoscopy, if only ovarian pathology (i.e. ovarian cyst) was present, if surgery was converted to laparotomy, or if more than one fertility-enhancing surgery was performed on the same patient.

All couples underwent routine baseline infertility investigations, including determination of midluteal serum progesterone levels and semen analysis. Diagnostic criteria for a severe male factor were a sperm count below 2 million/ml, sperm motility below 20% and morphology below 5% according to the Tygerberg strict criteria.[18] A hysterosalpingogram showing tubal pathology was the leading

indication to undertake surgery. Other indications included idiopathic infertility, suspected endometriosis and tubal pathology established at a previous diagnostic laparoscopy.

Laparoscopy utilised standard endoscopic equipment, excluding a CO_2 laser. Laparoscopic treatment included adhesiolysis, salpingostomy and ablation of endometriotic deposits following surgical techniques previously described.[8,9,11] No attempt at reconstruction of a proximal tubal occlusion was made, as laparoscopic re-anastomosis is a relatively new development, currently considered less precise than open microsurgery (International Federation of Fertility Societies Newletter, Spring 1998). Extensive pelvic irrigation was undertaken at the end of the surgical procedure. Antibiotics and anti-inflammatory drugs were given at the discretion of the surgeon and not as routine adjuvant treatment.

In the case of post-inflammatory tubal disease, patients were classified according to the Hulka classification of adnexal adhesions.[19] This staging system is based on four independent observations as follows:

Extent of adhesions. Stage I, over 50% of the ovarian surface visible, and stage II, less than 50% of the ovarian surface visible.

Nature of adhesions. Type A, filmy, avascular adhesions with good potential organ separation, and type B, dense, vascular adhesions with minimal potential organ separation.

Fimbrial patency. (): Fimbria patent, with no salpingostomy required, and F: fimbrial end occluded, salpingostomy required.

Isthmic patency. (): patent isthmus, i: and occlusion of the uterotubal junction or isthmus. Each of the adnexa were staged separately, and patients were classified according to the operation performed on the more favourable side.

In the presence of endometriosis, the revised American Society of Reproductive Medicine (ASRM) classification was applied.[20] Briefly, severity of disease is assessed in four categories depending on the presence and extent of peritoneal endometriosis, endometriomas and pouch of Douglas obliteration.

Patients were informed postoperatively about the procedures undertaken. Patients who had a favourable prognosis were counselled to await spontaneous conception, usually for a period of 9 - 12 months. Patients who failed to conceive during this period of time were asked to return for a follow-up visit in order to discuss other therapeutic options, notably ART. Patients with an unfavourable prognosis and patients who were found to be inoperable were advised to proceed with ART. *In vitro* fertilisation and embryo transfer (IVF/ET) was performed within the same Reproductive Medicine Unit. Patients followed standard treatment protocols with and without gonadotrophin-releasing hormone (GnRH) analogue down regulation. Patients under the age of 36 years had up to three embryos replaced, while up to four embryos were transferred in patients who were 36 years and older.

All patients in the study population were included in the outcome analysis. Patients were contacted between January and April 1998. Only patients who could not be traced at that time or who did not have a minimum interval of 6 months between the date of surgery and the time of follow-up were contacted again at a later stage. Patients were either interviewed telephonically or seen at a follow-up visit at the infertility clinic. Pregnancy was the main outcome measured. Only first clinical pregnancies post surgery, as documented on ultrasound or confirmed histologically following a miscarriage or ectopic pregnancy, were recorded. Patients who were lost to follow-up were regarded as not pregnant. Secondary outcome measures included PR according to type and degree of pelvic pathology (Hulka classification) and the outcome of IVF/ET in the same study population.

RESULTS

Between January 1994 and November 1997, 186 patients presenting with infertility fitted the criteria set out in the methodology. In nine patients the original case notes could not be accessed and these patients were withdrawn from the analysis. The remaining 177 patients represent the study population.

The mean duration of infertility was 5.3 years (range 2 - 12 years). The mean age of the women was 31 years (range 22 - 41 years), with no difference between women who achieved conception (32 years) and those who did not (31 years). Fifty-three patients had coexisting infertility factors. Thirty-six women were assessed as having ovulatory dysfunction and 17 men had a severe male factor on the basis of a p-pattern morphology. No negative association was demonstrated between these coexisting factors and the likelihood of conception.

One hundred and sixty-two patients were available for follow-up, which represents 91.5% of the study population. Fifteen couples were lost to follow-up. Nine couples divorced subsequent to treatment and none of them had conceived. The mean and the median duration of follow-up for all patients was 21.4 months (range 6 - 48 months) and 19 months respectively.

Twenty-four spontaneous conceptions resulted in 14 live births at term, 2 live births pre-term with favourable neonatal outcome, 2 first-trimester miscarriages and 6 ectopic pregnancies (EP). The spontaneous PR per patient for the entire group (N = 177) was 13.6%, with a live birth rate of 9%. The spontaneous extra-uterine PR was 3.4% per patient and accounted for 25% of all spontaneous conceptions. Twenty-five patients (14% of the study population) underwent IVF-ET.

A summary of the treatment outcome of the various surgical

procedures undertaken on the adnexum with least pathology is shown in Table I. 'No treatment' refers to patients with a normal adnexum unilaterally and evidence of post-inflammatory tubal disease on the contralateral side. Taken together as a group, patients with post-inflammatory tubal disease (all groups excluding endometriosis) had a statistically significantly lower live birth rate when compared with patients with endometriosis (6% v. 19.2%, $P = 0.028$).

Table I. Summary of spontaneous conceptions following surgical procedures

Procedure	Patients (*N*)	Pregnancies *N*	Pregnancies %	Live birth rate *N*	Live birth rate %
No treatment	19	6	31.5	3	15.8
Adhesiolysis	25	4	16	1	4
Salpingostomy	50	8	16	6	12
Inoperable	57	1	1.8	1	1.8
Endometriosis	26	5	19.2	5	19.2

A summary of the distribution of spontaneous pregnancies according to the four groups of tubal adhesions is demonstrated in Table II. Owing to the small numbers in each group, the results have to be viewed with caution. Conceptions occurred only in the first two disease categories, but were accompanied by a high ectopic pregnancy rate (2:4). The association between treatment outcome following salpingostomy and severity of disease is shown in Table III. Again, pregnancies occurred almost exclusively in the first two disease categories.

Eighty-nine patients, half of the study population, were counselled to proceed with IVF/ET. At the time of analysis only 25 patients had undergone IVF treatment and the majority (13 patients) underwent one treatment cycle only. Nine patients conceived following IVF/ET, resulting in a live birth PR of 36% per patient, 23.7% per cycle initiated and 33.3% per embryo transfer.

Table II. Spontaneous pregnancies in patients with post-inflammatory tubal adhesions

Classification	Patients (*N*)	Pregnancies (*N*)	Live births (*N*)
IA	11	3	0
IB	2	1	1
IIA	4	0	0
IIB	17	0	0

Table III. Spontaneous pregnancies in patients with post-inflammatory distal tubal occlusion

Classification	Patients (*N*)	Pregnancies (*N*)	Live births (*N*)
F	30	3	3
IAF	14	4	3
IBF	4	0	0
IIAF	5	0	0
IIBF	15	1	1

Discussion

Following 177 laparoscopies for reconstructive tubal surgery, a spontaneous intra-uterine pregnancy rate of 13.6% and a live birth rate of 9% were achieved.

When analysed according to pathology, patients with post-inflammatory tubal disease had a significantly lower live birth rate when compared with patients with endometriosis (6% v. 19.2%). Unfortunately the number of patients with endometriosis in our study was too small to undertake a meaningful outcome analysis according to the ASRM classification for endometriosis. The question therefore remains whether this difference in treatment outcome between post-inflammatory disease and endometriosis is secondary to the type or the severity of disease. A trend to improved treatment outcome in patients with endometriosis (with or without tubal occlusion) has been attributed to the lesser degree of tubal epithelial damage when compared with post-inflammatory tubal disease.[21]

The low intra-uterine PR following endoscopic reconstructive tubal surgery in patients with post-inflammatory tubal disease is not in keeping with other reports and requires further analysis. One reason frequently cited when analysing surgical results is the level of training of the surgeon undertaking the procedure. All cases in our study were undertaken by five experienced endoscopic surgeons, and we submit that surgical expertise is unlikely to be the main reason for poor success.

A second variable that could influence outcome is the follow-up of patients. We consider our follow-up adequate, as 91.5% of patients could be contacted and the median duration of follow-up was 19 months. Time to conception following reconstructive tubal surgery is controversial. Although a mean surgery-to-pregnancy interval of over 2 years has been reported, other authors have found a dramatic decrease in mean cycle fecundity at the end of the first postoperative year.[9,22] It is similarly controversial whether a prolonged surgery-to-pregnancy interval represents a steady state of subfertility or a prolonged phase of tubal regeneration which may be related to the initial degree of tubal damage.[14,22,23]

Thirdly, pregnancy outcome could be influenced by the presence of additional infertility factors. In our study no negative association between ovulatory dysfunction or male factor infertility (p-pattern morphology) and treatment outcome following surgery could be demonstrated. This would indicate that the state of subfertility, secondary to these coexisting infertility factors, is overshadowed by a more

serious state of subfertility due to tubal disease.

The most likely reason for the poor PR in our study is the degree of tubal damage. Most authors agree that the extent of tubal damage and amount of adhesive disease are the primary determinants of surgical success.[22,24,25] Tubal damage — and particularly inflammatory tubal damage — goes beyond the mere mechanical obstruction in most cases, and surgical restoration of tubal patency does not imply restoration of physiological function. This was demonstrated by Jacobs *et al.*[14] who reported a 75% tubal patency rate in women who failed to conceive by the end of 1 year following primary microsurgery for post-inflammatory tubal infertility. Since the degree of tubal damage is recognised as being the most important predictor of success, a careful assessment of pelvic pathology is essential. Several classification systems, aimed at judging the severity of tubal disease and correlating this with surgical outcome, have been published.[22] In this study, the Hulka classification was used, which is based on a staging system that utilises a simple yes/no judgement concerning four independent factors (extent of adhesions, nature of adhesions, fimbrial patency and isthmic patency). Our results demonstrate the low probability of conception in patients with extensive disease (IIA, IIB, IBF, IIF), as only one spontaneous pregnancy occurred in this group of patients. However, the overall pregnancy rate in patients with lesser disease remained low, particularly in patients with 'pure' hydrosalpinx. This could reflect a shortcoming of this classification system, which fails to evaluate tubal wall thickness, the quality of the tubal mucosa and the site of adhesions and may consequently underestimate the severity of disease. For these reasons we have subsequently changed to the classification system of the ASRM.[26]

If the low pregnancy rate in our study is secondary to the severity of disease, then we have to ask whether tubal disease in Africa is different to the rest of the world. There is mounting epidemiological evidence that African women have the highest rate of disease-induced infertility in the world, with a preponderance of infection-related causes.[27] This is most often the legacy of sexually transmitted diseases, miscarriages and unsafe delivery practices. It is likely that this preponderance of post-inflammatory tubal disease is associated with a high prevalence of severe disease. We are aware of only one report from this continent allowing us to compare our data. Kasia *et al.*[7] published the experience of the Yaounde General Hospital in Cameroon. Following 194 cases of endoscopic reconstructive tubal surgery, the PR following neosalpingostomies was 10.5%, a result similar to ours. The poor outcome following this procedure was attributed to the fact that 78% of patients presented with advanced tubal damage. The authors further considered the probability of a specific response to inflammation in African women which manifests as a 'frozen' pelvis with extensive, dense adhesions enveloping the adnexa, the uterus and the bowel. We are unaware of any study supporting this hypothesis. It is, however, our concern that the severe consequences of pelvic inflammatory disease represent poor health care rather than a population-specific inflammatory response.

Can we justify offering reconstructive tubal surgery as first-line therapy when in the same group of patients following IVF/ET a PR of 36% per patient and 33% per embryo transfer was achieved — indicating that most of the couples in this study would probably be fertile but for the mechanical obstruction? Over the last months we have carefully counselled patients on the treatment options, quoting success rates established in this study. Most patients continued to request surgery as first-line treatment. We believe that this choice is directly related to the current health policy of both the public and the private insurance sector, which tends to fund surgery and not ART. This brings us to the centre of the same debate which took place in industrialised countries many years ago. Following several reports on the poor treatment outcome in patients with extensive tubal damage, recommendations were made that these patients should be referred directly for IVF.[28] Watson *et al.*[29] pointed out that many patients were unable to access IVF and continued to request tubal surgery even if the quoted chance of success was as low as 1%. Lilford[15] concluded in an editorial that affluent couples were in a position to make an informed choice while indigent women could only do so if both methods were externally funded. While today in many industrialised countries ART is funded by both public and private health services, Lilford's comment remains pertinent to our own country. More recently the role of tubal surgery has again been challenged in the light of evidence that ART is more cost-effective in the treatment of tubal infertility than surgery.[16,30]

Post-inflammatory tubal infertility is a serious health problem affecting a large number of women in Africa. Future improvements in both preventive health care and endoscopic surgery may make reconstructive tubal surgery a truly effective first-line treatment for our patients. At present the results of our study strongly indicate that more patients are likely to benefit from ART than from reconstructive tubal surgery. In addition, cost-effective analyses support ART as first-line therapy in most instances. Unfortunately in this country ART is rarely externally funded and is commonly perceived as a luxury medical service. Unless we correct this perception and reallocate health funds so that ART services are as readily accessible to patients as surgery, the choice of treatment for tubal factor infertility in Africa will be of academic interest only.

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